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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
09/229,173	01/13/99	CHATTERJEE	D 0942.2800008

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EXAMINER	
HUTSON, R	
ART UNIT	PAPER NUMBER

1652 15
DATE MAILED: 07/30/01

Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trademarks

Office Action Summary

Application No.

09/229,173

Applicant(s)

CHATTERJEE, DEB K.

Examiner

Richard G Hutson

Art Unit

1652

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 21 May 2001.
- 2a) ☒ This action is **FINAL**.
- 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1,3-10,13,16,17,19,26,28,29 and 34-44 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1,3-10,13,16,17,19,26,28,29 and 34-44 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) 6,10,11.

- 4) ☐ Interview Summary (PTO-413) Paper No(s). _____
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other:

DETAILED ACTION

Applicants request for reconsideration of the rejection of the previous office action is acknowledged and the response to applicants traversal is presented below.

Claim Rejections - 35 USC § 112

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Claims 1, 3-10, 13, 16, 17, 19, 26, 28, 29 and 34-44 remain rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

The rejection is stated in the previous office action.

Applicants disagree with this rejection and submit that one of skill in the art could reasonably conclude that applicants had possession of the Tma DNA polymerase mutants encompassed by the rejected claims in the present application as filed.

Applicants submit that the Examiner has underestimated both the teaching of the present application and the level of skill in the art and the examiner has done nothing more than argue lack of literal support in the application, failing to present evidence or reasons why one skilled in the art would not reasonably conclude that applicants were in possession of the subject matter of the rejected claims. Applicants submit that the standard for fulfilling the written description requirement is whether the specification provides sufficient disclosure for one skilled in the art to readily envision a

Art Unit: 1652

representative number of members of the claimed genus. Applicants further submit that at the time the invention was made, the sequence of many DNA polymerases had been compiled and aligned, showing that the DNA polymerases could be divided into several distinct families based on sequence homology. These distinct families of polymerases share many conserved sites throughout the protein and domains responsible for the various activities of the polymerases have been identified. Further still it has been shown that a number of mutations in the different polymerases within a family appear to be conserved throughout the family such that they result in the same functional modification of many of the polymerases of that family. Based on this information available at the time of filing, applicants assert that one skilled in the art could readily envision a representative number of members of the claimed genus. Applicant is reminded that the rejected claims are not rejected based on a lack of enablement, but rather a lack of adequate written description.

The claimed genus includes all possible *Thermotoga maritima* (*Tma*)-DNA polymerase mutants which are modified at least two ways selected from the group consisting of (a) to reduce or eliminate the 3' 5' exonuclease activity of the polymerase; (b) to reduce or eliminate the 5' 3' exonuclease activity of the polymerase; and (c) to reduce or eliminate discriminatory behavior against dideoxynucleotides and methods of using and kits comprising said DNA polymerase mutants and genes encoding said DNA polymerase mutants. As stated in the previous office action, there is no disclosure of any particular structure to function/activity relationship in the claimed genus. While the specification provides the species, Asp³²³ → Ala³²³, (having reduced 3' → 5' exonuclease activity),

Application/Control Number: 09/229,173

Art Unit: 1652

Phe⁷³⁰ → Tyr⁷³⁰ (having reduced discriminatory behavior against a dideoxynucleotides) and Asp⁸ → Ala⁸, Asp¹³⁷ → Ala¹³⁷ or the deletion of 219 amino terminal amino acids of Tne DNA Polymerase (having reduced 5' 3' exonuclease activity) encompassed by these claims, the specification clearly does not disclose a representative number of species of the claimed genus which includes an infinite number of amino acid variants as well as additional chemical modifications of any *Tma* DNA polymerases. Even considering the substantial knowledge of the skilled artisan, as detailed by applicants, one could only envision a small number of additional species within the scope of the claimed genus. However, in view of the enormous breadth of the claimed genus, even these could in no way be considered to be representative of the entire genus. There is no disclosure of any particular structure to function/activity relationship in the claimed genus. The claimed genus of mutant *Tma* DNA polymerases has **no** structural limitation, only a functional limitation, thus the infinite number of species encompassed by this genus has not been adequately described by the few species disclosed in the specification.

Conclusion

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the

Application/Control Number: 09/229,173
Art Unit: 1652

shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Richard G Hutson whose telephone number is (703) 308-0066. The examiner can normally be reached on 7:30 am to 4:00 pm, M-F.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ponnathapy Achutamurthy can be reached on (703) 308-3804. The fax phone numbers for the organization where this application or proceeding is assigned are (703) 305-3014 for regular communications and (703) 305-3014 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0196.


**REBECCA E. PROUTY
PRIMARY EXAMINER
GROUP 1800**

Richard Hutson Ph.D.
July 27, 2001